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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,698	06/02/2005	Magnus Von Knebel-Doeberitz	03528.0145.00US00	9319

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EXAMINER	
AEDER, SEAN E	

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1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,698	VON KNEBEL-DOEBERITZ ET AL.	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

In view of cancellation of all previously pending claims and the addition of new claims 44-79 in the Reply of 3/23/09, restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 44, 51, 57, drawn to a frameshift polypeptide selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:120, SEQ ID NO:2, SEQ ID NO:3, and SEQ ID NO:118.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 45 link(s) inventions II-V, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 45. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group II, claim(s) 46, 47, 52, 53, 58, 59 as specifically drawn to a fragment peptide comprising a fragment of a frameshift polypeptide, wherein said fragment peptide comprises at least amino acids TIL of SEQ ID NO:20.

Group III, claim(s) 46, 48, 52, 54, 58, 60 as specifically drawn to a fragment peptide comprising a fragment of a frameshift polypeptide, wherein said fragment peptide comprises at least amino acids KQY of SEQ ID NO:21.

Group IV, claim(s) 46, 49, 52, 55, 58, 61 as specifically drawn to a fragment peptide comprising a fragment of a frameshift polypeptide, wherein said fragment peptide comprises at least amino acids GRR of SEQ ID NO:2.

Group V, claim(s) 46, 50, 52, 56, 58, 62 as specifically drawn to a fragment peptide comprising a fragment of a frameshift polypeptide, wherein said fragment peptide comprises at least amino acids KAE of SEQ ID NO:3.

Group VI, claim(s) 63 as specifically drawn to a pharmaceutical composition comprising a set of at least three frameshift polypeptides A, B, and C; wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, and SEQ ID NO:119.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 64 and 73 link(s) inventions VII-XII, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 64 and 73. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group VII, claim(s) 65, 66, 74 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide A has SEQ ID NO:20 and the three amino acids are TIL .

Group VIII, claim(s) 65, 67, 75 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide A has SEQ ID NO:21 and the three amino acids are KQY.

Group IX, claim(s) 65, 68, 76 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide B has SEQ ID NO:2 and the three amino acids are GRR.

Group X, claim(s) 65, 69, 77 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide B has SEQ ID NO:3 and the three amino acids are KAE.

Group XI, claim(s) 65, 70, 78 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide C has SEQ ID NO:11 and the three amino acids are RLS.

Group XII, claim(s) 65, 71, 79 as specifically drawn to a pharmaceutical composition and a kit comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is

selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120, comprising at least 3 amino acids of a mutated part of the corresponding frameshift polypeptide, wherein the frameshift polypeptide C has SEQ ID NO:12 and the three amino acids are KAW.

Group XIII, claim(s) 72 as specifically drawn to a pharmaceutical composition comprising a set of at least three frameshift polypeptides A, B, and C; wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, and SEQ ID NO:120.

The inventions listed as groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that the groups I-XII do not relate to a specific polypeptide sequence which would constitute a technical feature linking groups I-XII. Rather, the technical feature linking groups I-XII appears to be that they all relate to the special technical feature of a variant of TAF1b polypeptide.

However, Yang et al (Molecular and Cellular Biology, November 1996, 16(11):6603-6616) teaches GCD2, which is a variant of TAF1b polypeptide (see pages 604-605, in particular).

Therefore, the technical feature linking the inventions of groups I-XII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I is generic to a plurality of disclosed patentably **distinct species of frameshift polypeptides** comprising the following: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:120, SEQ ID NO:2, SEQ ID NO:3, and SEQ ID NO:118. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods

which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Group VI generic to a plurality of disclosed patentably **distinct species of sets of at least three frameshift polypeptides A, B, and C; wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, and SEQ ID NO:119**. Each set represents a distinct species. Applicant must elect a single set. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Groups VII-XII are generic to a plurality of disclosed patentably **distinct species of pharmaceutical compositions and a kits comprising a set of at least three fragment peptides each being a fragment of a frameshift polypeptide A, B, or C, wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119, SEQ ID NO:120; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, SEQ ID NO:119, and SEQ ID NO:120**. Each set represents a distinct species. Applicant must elect a single set identified by the SEQ ID NOs of the frameshift polypeptides. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Group XIII is generic to a plurality of disclosed patentably **distinct species of pharmaceutical compositions comprising a set of at least three frameshift polypeptides A, B, and C; wherein A is selected from the group consisting of: SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:119; wherein B is selected from SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:118; and C is selected from SEQ ID NO:11, SEQ ID NO:12, and SEQ ID NO:120.** Each set represents a distinct species. Applicant must elect a single set identified by the SEQ ID NOs of the frameshift polypeptides. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642